IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF TEXAS

TEXARKANA DIVISION

VERA EASTER	§	
Vs.	§	CIVIL ACTION NO. 5:03-CV-141
AVENTIS PASTEUR, INC., ET AL.	§	

MEMORANDUM OPINION AND ORDER

1. Introduction.

The court grants the defendants' motion to preclude the proposed testimony of the plaintiffs' expert witnesses pursuant to Fed. R. Civ. P. 401, 702, 703, and *Daubert* insofar as the motion seeks to preclude Dr. Jeffrey Bradstreet's proposed testimony concerning specific causation.

2. Factual Background and Procedural Posture.

In this case, the plaintiffs allege that the thimerosal contained in the pediatric vaccines administered to Jordan Easter caused Jordan to suffer neurological injuries. Thimerosal was developed by Eli Lilly in the late-1920s and contains ethyl-mercury. Thimerosal was widely used in the United States as a preservative in pediatric vaccines until recently, following the Food and Drug Administration's efforts to eliminate its use in those vaccines because of its mercury content. The plaintiffs contend that some children are genetically susceptible to mercury poisoning and cannot excrete or otherwise eliminate the mercury in the vaccine preservative.

Jordan Easter has autism. According to the medical records, Jordan has been diagnosed with Autistic Disorder meeting the DSM-IV criteria. *See* University of Arkansas Medical Services,

Department of Pediatrics, Developmental Medical Evaluation of Jordan Easter. Under the DSM-IV criteria, three conditions must be present: (1) impairment in social interaction; (2) problems in communication; and (3) unusual or severely limited activities or interests.

The plaintiffs have conceded that they cannot prove, in Jordan's case, that his autism was caused by thimerosal. This is because Jordan does not meet the genetic profile for children who, according to the plaintiffs, are at an increased risk for developing autism caused by thimerosal in pediatric vaccines. Because the plaintiffs have conceded they cannot prove that Jordan's autism was caused by thimerosal, they seek to recover on a claim that several co-morbid conditions suffered by Jordan were instead caused by, or contributed to by, Jordan's exposure to the thimerosal contained in the pediatric vaccines.

The defendants have filed a motion to preclude the testimony of the plaintiffs' causation experts. First, the defendants move to exclude the plaintiffs' experts on "general causation." Under Texas products liability law, the plaintiffs in a case like this one must prove both general and specific causation. *See In re Norplant Products Liability Litig.*, 215 F. Supp. 2d 795 (E.D. Tex. 2002). "General causation" refers to the ability of a product, in this case, thimerosal, to cause a particular injury. In the present case, one component of the motion to preclude asserts that the plaintiffs have no reliable proof that, as a scientific matter, thimerosal causes autism or autism spectrum disorders in a vulnerable sub-population of children.

A second component of the motion to preclude involves whether the plaintiffs have established by reliable evidence that the injury caused to the specific plaintiff, Jordan Easter, was in fact caused by the product at issue in the case. Dr. Jeffrey Bradstreet is the plaintiffs' sole expert on specific causation. In a recent affidavit tendered in response to the defendants' motion to

preclude, Dr. Bradstreet describes the co-morbid conditions he seeks to attribute to mercury poisoning. Dr. Bradstreet's affidavit states that these conditions include: sensory processing disorders; attention deficits and hyperactivity and distractibility; cognitive deficits; sleep disorder; mood disorder; uncontrollable tantrums; auditory processing disorders; aggression and combativeness; hypotonia (low muscle tone); joint inattention; abnormal fine motor perception; oral sensitivity; inability to jump. (Bradstreet Aff. ¶ 4). According to Dr. Bradstreet "[a]ll of these signs and symptoms can, based on various reports included in my bibliography, be attributed to mercury." *Id.* The defendants move to preclude Dr. Bradstreet's opinion that the co-morbid conditions suffered by Jordan were caused by thimerosal.

3. Discussion.

For purposes of this opinion, this court may assume, *arguendo*, that the plaintiffs have demonstrated sufficiently reliable epidemiological and other proof to support the theory that thimerosal in vaccines can cause autism and/or autism spectrum disorders in a predisposed sub-population of children in the United States. Likewise, the court may look past some of the defendants' specific critiques of Dr. Bradstreet–that he never examined Jordan before rendering an opinion of mercury poisoning and that he failed to insist on additional testing with respect to this particular child. On this record, what renders Dr. Bradstreet's opinion inadmissible is the plaintiffs' concession that they cannot prove that Jordan Easter's autism was caused by thimerosal.

The question of specific causation addresses whether thimerosal caused the specific injuries alleged by a particular plaintiff. To establish specific causation, the plaintiffs' expert witnesses must "demonstrate a 'specific train of medical evidence' connecting the illness to the product." *Newton v. Hoffman-Laroche, Inc.*, 243 F. Supp. 2d 672, 682 (W.D. Tex. 2002). Differential diagnosis is a

well-recognized methodology for determining specific causation in a particular plaintiff.

Differential diagnosis is "a process whereby medical doctors experienced in diagnostic techniques provide testimony countering other possible causes . . . of the injuries at issue." *Hines v. Consolidated Rail Corp.*, 926 F.2d 262, 270 n.6 (3d Cir.1991). A reliable differential diagnosis typically, though not invariably, is performed after "physical examination, the taking of medical histories, and the review of clinical tests, including laboratory tests," and generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is most likely. *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir.1999). "A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion." *Id.* at 265; *see also Cavallo v. Star Enterprise*, 892 F. Supp. 756, 771 (E.D. Va. 1995), *rev'd in part on other grounds*, 100 F.3d 1150 (4th Cir.1996)("If other possible causes of an injury cannot be ruled out, or at least the probability of their contribution to causation minimized, then the 'more likely than not' threshold for proving causation may not be met").

Given the plaintiffs' concession in their response brief that they cannot prove that Jordan Easter's autism was caused by thimerosal, the defendants argue:

> Fourth, and most importantly, there is no scientifically recognized methodology by which Dr. Bradstreet could reliably conclude that the minor's conditions, such as mental retardation and ADHD, have a cause separate from whatever caused his autism–concededly not defendants' vaccines. The mere fact that an injured child previously had been exposed to mercury in the same quantities as virtually all children is far from enough to permit a reliable differential diagnosis in a doctor's office or hospital that some of the minor's injuries were caused by mercury toxicity, *rather than by whatever caused his autism*."

(Defendants' Reply Brief, p. 4)(emphasis in original and also added). Under the facts of this case, the court agrees.

The difficulty with the plaintiffs' position is that there is a known association between autism and the various co-morbid conditions suffered by Jordan Easter. For example, the parties agree that Jordan Easter suffers from diminished mental capacity, although it is not clear that he actually meets the definition of mentally retarded. *See* Johnson Report, ¶ 41 (concluding that Jordan Easter suffers from Autistic Disorder, with co-morbid ADHD and possible mild mental retardation) ¶ 31 (concluding that Jordan's IQ score was 67 and thus borderline under the definition for mental retardation). Although the two conditions do not necessarily co-exist, approximately 70% of autistic individuals also suffer from mental retardation. *See* Fombonne Report, ¶¶ 25, 42. Moreover, as Dr. Fombonne explained in his testimony at the *Daubert* hearing, the other co-morbid conditions, including Jordan's sensory processing disorders, auditory neglect, speech and language disorders, mood disorders, tantrums, and sleep disorders, are all conditions which are either subsumed within the DSM-IV criteria for diagnosing autism or, like mental retardation, are conditions that are regularly associated with autistic patients.

Given that these symptoms and conditions are so regularly associated with autism, a medical doctor rendering a differential diagnosis would need to be able rule out all of the potential causes of the patient's condition, including autism, before determining that the co-morbid conditions were caused by something other than what had caused the autism. Although it is true that the co-morbid conditions are not suffered exclusively by all persons diagnosed with autism, it is equally true that the co-morbid conditions are suffered by autistics who have never been exposed to thimerosal-containing pediatric vaccines. As Dr. Fombonne testified, these co-morbidities are suffered even

by his Canadian autistic patients, and thimerosal is not used in Canada. Therefore, even if thimerosal can be attributed to *some* of the instances of the co-morbid conditions, it cannot be the cause of *all* of the occurrences of these co-morbidities in individuals diagnosed with autism. Given these facts, and further given the high correlation between the conditions, at least one reasonable assumption is that, thimerosal aside, whatever caused a person's autism also caused the co-morbid conditions. Although the plaintiffs have conceded that they cannot prove that *thimerosal* caused Jordan Easter's autism, they have also not explained why the cause of the autism (whatever it may be) is not also the cause of the co-morbid conditions. Under this record, Dr. Bradstreet's inability to rule *in* thimerosal as the cause of Jordan's autism ultimately renders inadmissible his opinion that thimerosal (but not whatever caused the autism) was the cause of the various co-morbidities regularly associated with autism.

The court addressed an analogous situation in *Kelley v. American Heyer-Schulte Corp.*, 957 F. Supp. 873 (W.D. Tex. 1997). In that case, the plaintiff suffered from Sjogren's Syndrome which caused various symptoms. She could not prove that her breast implants had caused Sjogren's Syndrome. Nevertheless, she sought to recover on a claim that her implants caused the various symptoms comprising Sjogren's Syndrome. The court rejected her expert's testimony, noting:

> Given that the Plaintiff has Sjogren's Syndrome, it is impossible for the Plaintiff to establish that "but for" her breast implants, she would not have sicca symptoms–after all, the very symptoms she wishes to blame her breast implants for are also caused by her inflammatory disorder. Thus, if the Plaintiff cannot show that breast implants caused her Sjogren's Syndrome, then the Plaintiff cannot establish that her dry eyes were caused in fact by the breast implants.

Kelley, 957 F.Supp. at 880.

In addition, the court observed:

> The Plaintiff argues that Sjogren's Syndrome is just a descriptive term for a constellation of symptoms. Therefore, the Plaintiff concludes, she should be able to show that breast implants cause her individual sicca symptoms, even if she cannot establish that her breast implants cause Sjogren's Syndrome. This argument is specious. If Sjogren's Syndrome is not a classic disease but rather just a set of symptoms, then failure of the Plaintiff to establish that breast implants cause "Sjogren's Syndrome" amounts to a failure by the Plaintiff to establish that breast implants cause the symptoms of that condition.

Id. at n. 6.

This case might be viewed differently from *Kelley* in one sense: no one contends that Autistic Disorder *causes* diminished mental capacity. The two conditions are, however, so regularly associated that it is reasonable to assume that the cause of the autism may also be the cause of the mental incapacity. Although the plaintiffs point to studies demonstrating the toxicity of mercury, mercury is not the only cause of neurological injuries. What is lacking in this case is a sufficient explanation for why the cause of the autism suffered by Jordan Easter is not also the cause of the co-morbid conditions claimed to be caused by thimerosal.

In addition, several of the studies asserted by the plaintiffs to link thimerosal with neurological disorders are actually autism studies. For example, Blaxill's chart illustrated an increase in autism diagnoses in the 1990s. This increase, according to plaintiffs, corresponded with an increase in the number of thimerosal-containing vaccines administered in the United States. In addition, Dr. Jill James presented an unpublished study, also relied on by plaintiffs, to the Defeat Autism Now! Conference in 2004. That study addressed polymorphisms present in autistic children. Likewise, in his report, Dr. Bradstreet indicates that he had been involved in studies relating to chelation therapies. Again, these therapies were administered to autism patients. The plaintiffs point

to Holmes' study on hair samples. These, too, involved hair samples taken from autistic children and suggest that autistic children cannot excrete mercury. Finally, Dr. Bradstreet's report references the mouse studies performed by Mady Hornig of Columbia University. Horning's study involved a comparison of the behavior of mice to behaviors exhibited by autistic children. The plaintiffs' inability to prove that Jordan Easter's autism was caused by thimerosal in this particular case renders suspect Dr. Bradstreet's ability to utilize these studies to conclude reliably that thimerosal caused the co-morbid conditions independently from whatever caused the autism.

This is not to say that the efforts of Dr. Bradstreet are in vain or subject to insurmountable obstacles. This order signals no criticism of any past or future scientific attempts to parse the causes of autism from the causes of the co-morbidities at the heart of the plaintiffs' case. The court certainly does not find *an absence* of any link between the thimerosal in pediatric vaccines and neurological disorders or autism suffered by some children. Such a conclusion would make the court more ambitious than Merck's own scientists, who, according to the proof referenced in the plaintiffs' brief, recognized that thimerosal and its associated mercury load might be problematic in pediatric vaccines. Thus, the court expresses no opinion on the question presented by one aspect of the motion to preclude–the reliability and admissibility of the plaintiffs' experts' testimony on general causation. That decision is unnecessary at this time.

This precious child, whose innocence in all of this is undisputed by any of the parties or this court, finds himself at a place where the law simply demands more than his able counsel and experts have offered. This is because the burden of proof in a case like this one rests with the plaintiffs to demonstrate specific causation. The burden is not on the defendants to show that thimerosal *did not* cause the conditions. The beginning and the end of this ruling, therefore, is that the record will not

permit the court to admit Dr. Bradstreet's opinion on specific causation because of the concession that the plaintiffs cannot prove that Jordan Easter's autism was caused by thimerosal.

4. Conclusion.

The court grants the defendants' motion to preclude the testimony of Dr. Jeffery Bradstreet with respect to specific causation.

SIGNED this 14th day of February, 2005.

T. JOHN WARD
UNITED STATES DISTRICT JUDGE